IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9055

Bartle, J. May 3, 2013

Jean Ninemire ("Ms. Ninemire" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2006, claimant submitted an amended Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed at least 350 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated May 25, 2001, Dr. Evans attested in Part II of Ms. Ninemire's Green Form that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

60%.[3] Based on such findings, claimant would be entitled to Matrix A-1,[4] Level II benefits in the amount of $471,345.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, F.S. Neuer, M.D., stated, "There is moderate mitral regurgitation." Dr. Neuer, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In May, 2006, the Trust forwarded the claim for review by Jeremy I. Nadelmann, M.D., F.A.C.C., one of its auditing

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3. Dr. Evans also attested that claimant suffered from moderate aortic regurgitation. This condition is not at issue in this claim.

4. Dr. Evans also stated in claimant's Green Form that Ms. Ninemire did not have mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Given our disposition regarding claimant's level of mitral regurgitation, however, we need not address whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

cardiologists. In audit, Dr. Nadelmann concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Ninemire had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Nadelmann explained, "The [claimant] has only mild mitral regurgitation seen in multiple views. In addition, the color gain is too high and the color persistence is excessive thereby overestimating the true degree of mitral regurgitation."

Based on Dr. Nadelmann's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Ninemire's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted an affidavit of Gregory R. Boxberger, M.D., F.A.C.C. In his affidavit, Dr. Boxberger stated that claimant had moderate mitral regurgitation and noted, "Based on the Singh criteria, I found multiple frames where the RJA/LAA ratio was greater than 20%." Claimant argued, therefore, that there was a reasonable medical basis for her claim because two Board-Certified cardiologists and the original reviewing

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Ninemire's claim.

cardiologist independently agreed that she had moderate mitral regurgitation. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his **personal opinion** ... and the 'reasonable medical basis' standard." (emphasis in original.)

The Trust then issued a final post-audit determination, again denying Ms. Ninemire's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Ninemire's claim should be paid. On December 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6812 (Dec. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 20, 2007, and claimant submitted a sur-reply on March 15, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Ninemire repeats the arguments she made in contest, namely, that the opinions of Dr. Evans and Dr. Boxberger provide a reasonable medical basis

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are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

for the finding of moderate mitral regurgitation. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and the auditing cardiologist, Dr. Nadelmann. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Ninemire contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of an RJA/LAA ratio of 20% by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim because Dr. Evans and Dr. Boxberger do not address Dr. Nadelmann's specific findings, nor do they identify any high-velocity, sustained jets of mitral regurgitation seen in multiple consecutive frames. The Trust also contends that Dr. Evans failed to rebut Dr. Nadelmann's finding that the "degree of mitral regurgitation is over-estimated because of excessive color gain and color persistence on the echocardiographic study." Finally, the Trust argues that inter-reader variability does not establish a reasonable medical basis for Ms. Ninemire's claim because Dr. Nadelmann specifically determined that there was no reasonable medical basis for the attesting physician's finding.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no

reasonable medical basis for the attesting physician's finding that Ms. Ninemire had moderate mitral regurgitation. Specifically, Dr. Vigilante determined that:

> I reviewed the Claimant's echocardiogram of May 25, 2001.... Appropriate Nyquist limits were used at 69 cm per second in the apical four chamber and apical two chamber views. However, for no identifiable reason, [the] Nyquist limit was suddenly decreased from 69 cm per second to 60 cm per second in the apical two chamber view when evaluating the mitral regurgitant jet. In addition, there was clear evidence of excessive color gain noted in all views when color flow was used. There was color artifact seen outside of the cardiac chambers. In addition, there was inappropriate demonstration of low velocity flow.
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> Visually, mild posterolaterally directed mitral regurgitation was noted in the parasternal long axis and apical views. I digitized those cardiac cycles in the apical four chamber and apical two chamber views in which the mitral regurgitant jet could be best identified. I then determined the RJA and LAA on several representative cardiac cycles. The largest representative RJA in the apical four chamber view was 2.4 cm2. I was able to exclude low velocity, non-mitral regurgitant flow with excessive color gain by evaluating this jet in real-time. The RJA was less than 2.0 cm2 in the apical two chamber view. I determined that the LAA was 19.6 cm2. Therefore, the largest representative RJA/LAA ratio was 12%. The RJA/LAA ratio never approached 20%. Most of the RJA/LAA ratios were less than 10%. There were no sonographer measurements of the supposed RJA on the tape.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, claimant does not adequately refute the findings of the auditing

cardiologist or the Technical Advisor. Claimant does not rebut Dr. Nadlemann's determination that "the color gain is too high and the color persistence is excessive thereby overestimating the true degree of mitral regurgitation."[8] Nor does claimant challenge Dr. Vigilante's conclusion that "the largest representative RJA/LAA ratio was 12%" and that "[m]ost of the RJA/LAA ratios were less than 10%."[9] Neither claimant nor her experts identified any particular error in the conclusions of the auditing cardiologist and Technical Advisor. Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Moreover, we disagree with claimant that the opinions of her physicians establish a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents lead us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist

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8. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his personal opinion for the diagnosis of the attesting physician.

9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Nadelmann and Dr. Vigilante both found, and claimant does not adequately dispute, that the echocardiogram used improperly high color gain. Dr. Vigilante also determined that the Nyquist limit was set too low and that the supposed regurgitant jet included low velocity flow, which was not representative of true mitral regurgitation. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Ninemire had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist determined that claimant had only mild mitral regurgitation and

the Technical Advisor concluded that claimant's echocardiogram demonstrated RJA/LAA ratios of at most 12%. Adopting claimant's argument that inter-reader variability would expand the range of moderate mitral regurgitation by ±15% would allow a claimant to recover benefits with a RJA/LAA as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[10]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Ninemire's claim for Matrix Benefits.

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10. Moreover, the Technical Advisor specifically took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."